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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,052	07/14/2003	Yasumichi Hitoshi	021044-004010US	7655

20350 7590 05/08/2006

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EXAMINER	
HALVORSON, MARK	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,052	HITOSHI ET AL.	
	Examiner	Art Unit	
	Mark Halvorson	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 1-44 are pending and are currently under prosecution.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1, claims 1-23, drawn to a method for **identifying a compound** that modulates a cell cycle arrest, the method comprising the steps of: contacting a cell comprising a target polypeptide; determining the physical effect of the compound upon the target polypeptide and determining the chemical or phenotypic effect of the compound upon a cell comprising the target polypeptide, classified in class 435, subclass 325.

Group 2, claim 24-33, drawn to a method of **modulating cell cycle arrest** in a subject, the method comprising the step of administering to the subject a therapeutically effective amount of a **compound isolated in a method** comprising the steps of: contacting a cell comprising a target polypeptide; determining the chemical or phenotypic effect of the compound upon a cell comprising the target polypeptide, classified in class 514, subclass 2.

Group 3, claim 34, drawn to a method of **modulating cell cycle arrest** in a subject, the method comprising the step of administering to the subject a therapeutically effective amount of a target polypeptide, classified in class 514, subclass 2.

Group 4, claim 35, drawn to a method of modulating cell cycle arrest in a subject, the method comprising the step of administering to the subject a therapeutically effective amount of a **nucleic acid** encoding a target polypeptide, classified in class 514, subclass 44.

Group 5, claims 36, 37 drawn to a CK2-specific siRNA molecule comprising SEQ ID NO:37 and its complement, classified in class 536, subclass 24.5.

Group 6, claim 38, drawn to a method **of inhibiting the expression of a CK2 gene** in a cell, the method comprising contacting the cell with a CK2-specific siRNA comprising SEQ ID NO:37, classified in class 435, subclass 6.

Group 7, claims, 39, 40 drawn to a **PIM1-specific siRNA molecule** comprising SEQ ID NO:38 and its complement, classified in class 536, subclass 24.5.

Group 8, claim 41, drawn to a method of **inhibiting the expression of a PIM1 gene** in a cell, the method comprising contacting the cell with a CK2-specific siRNA comprising SEQ ID NO:38, classified in class 435, subclass 6.

Group 9, claims, 42, 43 drawn to a **HBO1-specific siRNA** molecule comprising SEQ ID NO:39 and its complement, classified in class 536, subclass 24.5.

Group 10, claim 44, drawn to a method of **inhibiting the expression of a HBO1 gene** in a cell, the method comprising contacting the cell with a CK2-specific siRNA comprising SEQ ID NO:39, classified in class 435, subclass 6.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions 5, 7 and 9 as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions. The inventions are drawn to proteins that are structural different and thus functionally different.

The product of Group 5 is not used in the method of Groups 1-4, 8 and 10. The product of Group 7 is not used in the methods of Groups 1-4, 6 and 10. The product of Group 9 is not used in the methods of Groups 1-4, 6 and 8.

Inventions 5 and 6, Inventions 7 and 8, Inventions 9 and 10 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the siRNA of inventions, 5, 7, and 9 can be used to used for probes.

The methods of Groups 1-4, 6, 8, 10 are materially distinct methods which differ at least in objectives, method steps and reagents. Group 1 is drawn to a drawn to a method for identifying a compound that modulates a cell cycle arrest. Group 2 is drawn to a drawn to a method of modulating cell cycle arrest in a subject. Group 3 is

drawn to a method of modulating cell cycle arrest in a subject, the method comprising the step of administering to the subject a therapeutically effective amount of a target polypeptide. Group 4 is drawn to a method of modulating cell cycle arrest in a subject, the method comprising the step of administering to the subject a therapeutically effective amount of a nucleic acid encoding a target polypeptide. Group 6 is drawn to a method of inhibiting the expression of a CK2 gene in a cell. Group 8 is drawn to a method of inhibiting the expression of a PIM1 gene in a cell. Group 10 is drawn to a method of inhibiting the expression of a HBO1 gene in a cell. Each of the groups employ different reagnets to accomplish different objectives that comprise different method steps. Searching all of the groups with all of the different objectives, method steps, and reagents would invoke a high burden of search.

SPECIES ELECTION

4. This application contains claims directed to the following patentably distinct species of the claimed invention.

Groups 1-4 are further subject to election of a single disclosed species.

Claims 1, 23, 34, 35 drawn to a polypeptides,
claim 16 drawn to nucleic acids,
are generic to groups 1-4 as they are drawn specifically to methods of using polypeptides and nucleic acids, wherein the species are drawn to

polypeptides encoded by the nucleic acid of SEQ ID NOS: 14, 2 4, 6, 8, 10 12, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, and 36.

nucleic acids of SEQ ID NOS: 13, 1 3, 5, 7, 9 11, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, and 35;

Claims 1, 16, 23, 34, 35 are drawn to polypeptides and nucleic acids that fail the Harnisch test. In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group share, as a whole, a substantial structural feature disclosed as being essential to that utility. However, the molecules of each of claims , 16, 23, 34, 35 do not share as a whole, a substantial structural feature, one with the other because claims 1, 23, 34, 35 are drawn to polypeptides with structurally different polypeptide sequences, claim 16 is drawn to nucleic acids with structurally different nucleic acid sequences and therefore do not have as a group similar structures.

Thus each of these claims fail the Harnish test and they do not meet the requirements to be accorded Markush practice under MPEP 803.02. Applicant must elect not only a single Group but also a **single polypeptide or nucleic acid** for examination.

(ii). Group 1 is further subject to election of one of the disclosed species.

Claim 1 is generic to a plurality of chemical or phenotypic effects that have different structures and functions wherein the species are (a) enzymatic activity (b) cellular proliferation.

(ii)(a). Species (a) is further subject to restriction because claim 2 is generic to a plurality of disclosed patentably distinct species of **enzymatic activity**, the enzymatic activities being (a) **nuclease activity**, (b) **kinase activity**, (c) **lipase activity**, (d) **transferase activity**, (e) **phosphatase activity** and (f) **acetylase activity.**

(ii)(b). Species (b) is further subject to restriction because claim 4 is generic to a plurality of patentably distinct measures of cellular proliferation, the cellular proliferation being measured by (I) **DNA synthesis** or (II) **fluorescent marker level.**

(ii)(b)(I) Species (I) is further subject to restriction because claim 5 is generic to a plurality of patentably distinct measure of DNA synthesis, the DNA synthesis

being measured by (A) **thymidine incorporation**, (B) **BrdU incorporation**, (C) **Hoescht staining.**

(ii)(b)(II) Species (II) is further subject to restriction because claim 6 is generic to a plurality of patentably distinct fluorescent markers, the fluorescent markers being (A) **cell tracker dye** or (B) **green fluorescent protein**.

(iii). Group 1is further subject to election of one of the disclosed species.
Claim 1 is generic to a plurality of different host cancer cells that have different structures and functions wherein the different host cancer cells are (a) **breast** (b) **prostate**, (c) **colon** (d) **lung** (e) **transformed cell line** (f) **p53 null or mutant** or (g) **p53 wild type**.

(iii)(e) Species (e) is further subject to restriction because claim 12 is generic to a plurality of patentably distinct transformed cell lines, the transformed cell lines being (I) **A549**, (II) **PC3**, (III) **H1299**, (IV) **MDA-MB-231**, (V) **MCF7**, or (VI) **HeLa**

(iv). Group 1 is further subject to election of one of the disclosed species.
Claim 1 is generic to a plurality of different compounds that have different structures and functions wherein the compounds are (a) **an antibody**, (b) a **small organic molecule**, (c) **an antisense molecule**, (d) **a peptide wherein the peptide is circular**.

(v). Group 2 is further subject to election of one of the disclosed species.
Claim 24 is generic to a plurality of different compounds that have different structures and functions wherein the compounds are (a) an **antisense molecule**, (b) an **antibody**, (c) **a peptide wherein the peptide is circular** or (d) an **siRNA** molecule

5. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Note:

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See

"Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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571-272-6539

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SUPERVISORY PATENT EXAMINER